IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 9 CASES LISTED IN EXHIBIT A OF DEFENSE NOTICE OF ADOPTION	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF DANIEL ELLIOTT, M.D.[1]

In seeking to exclude certain general opinions of Dr. Daniel Elliott in this Wave 10, Defendants Ethicon, Inc., Ethicon LLC, and Johnson & Johnson (collectively, "Ethicon" or "Defendants") reiterate nearly verbatim arguments already asserted in previous Waves of the MDL. Plaintiffs accordingly incorporate their Wave 3 Memorandum in Opposition to Defendants' Motion to Exclude Certain General Opinions of Daniel Elliott, M.D. (ECF No. 2952), as if fully set forth herein. Defendants otherwise raise new arguments based on statements pulled out of context from an article on which Dr. Elliott was a corresponding author. When read with full context the article support Dr. Elliott's opinions. For the reasons previously stated in Doc. 2952, and for the additional reasons set forth herein, Defendants' Motion to Exclude Certain General Opinions of Daniel Elliott, M.D., should be denied.

BACKGROUND

Dr. Daniel S. Elliott is an associate professor of urology in the section of Female Urology and Reconstructive Surgery at the Mayo Clinic Graduate School of Medicine in Rochester,

[1] This response is nearly identical to Plaintiffs' response to the same motion that was filed in Wave 10. However, this brief includes a brief response to certain arguments that Ethicon made in its Wave 10 reply. The new argument is in Section I(B).

Minnesota. He has treated hundreds of patients with mesh-related complications. For over 15 years, he has specialized in treating urinary incontinence in women. He has delivered numerous lectures on treatment options for stress urinary incontinence (SUI) in women, including the limitations of each. He is an editor or reviewer for 15 urologic and gynecologic journals and has reviewed all readily available medical literature on SUI treatment options. He has also reviewed an extensive number of internal Ethicon documents and depositions of its personnel in developing his opinions in these cases.

Dr. Elliott has extensive experience implanting both naturally made and synthetic slings to treat SUI, including polypropylene slings. In fact, synthetic slings were his primary treatment for SUI prior to August 2013. He implanted several hundred synthetic slings during that time period. He has treated thousands of women with complications from mesh.

LEGAL STANDARD

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702.

If the witness is suitably qualified, the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents "scientific knowledge," meaning that it is supported by appropriate validation. The second issue is whether the evidence

would assist the jury. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995); *see also Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993) (discussing "fit").

ARGUMENT

I. Dr. Elliott should be permitted to testify that the TVT devices are unsafe for the surgical treatment of SUI.

Ethicon seeks to limit Dr. Elliott from testifying about the safety of the TVT devices by presenting out-of-context and incomplete statements made generally about midurethral slings in an article for which Dr. Elliott was only a corresponding author. Ethicon then compares these statements to those that Dr. Elliott made specifically about Ethicon's TVT Devices in his Rule 26 Reports. In proper context, the article actually corroborates Dr. Elliott's expert reports. But either way, the article is a basis for cross-examination, not for exclusion of Dr. Elliott's opinions.

A. Dr. Elliott's opinions do not contradict statements made in an article for which he was a corresponding author, and even if they did, that would be grounds for cross-examination, not for exclusion.

Defendants cite this Court's decision in *Wilkerson v. Boston Scientific Corp.*, *Wilkerson v. Bos. Sci. Corp.*, No. 2:13-CV-04505, 2015 WL 2087048, at *15 (S.D.W. Va. May 5, 2015), as "directly on point," but it is not the same situation. In that case, this Court precluded expert testimony because the expert "employed less intellectual rigor" when forming his opinion than he did "when writing studies in his field." *Id.* at *15. In that case, the expert stated in an article to his peers that "[t]he etiology of mesh sling complication is a matter of conjecture." *Id.* Here, however, Dr. Elliott corresponded on an article written by a colleague that actually supports his Rule 26 Expert Reports regarding Defendants' TVT Devices:

Dr. Elliott's Expert Reports	2019 Article
"Ethicon has realized the need for decreasing complications rates from its heavyweight, small pore meshes through	"It has been identified that several qualities of the implanted material, such as pore size, weave, and fiber

the development of lighter weight materials, which elicit a lower inflammatory response in the human body." Def. Ex. C, TVT Report at 18; *see also* Def. Ex. D, TVT-O Report at 18-19.	diameter, were important in determining the body's reaction to the material." Def. Ex. G, 2019 Article at 19.
"[T]here is a consensus that synthetic meshes that are low-weight, large-pore size, high porosity, monofilament, and capable of maintaining their elasticity under load will have the better results with fewer complications … mesh stiffness, porosity and the pore size of the mesh are of critical importance." Def. Ex. C, TVT Report at 9-10; Def. Ex. D, TVT-O Report at 9-10.	"Currently, the ideal mesh should be large pore … and monofilament (type I) … use of smaller pore size meshes (type III) was associated with mesh encapsulation and high rates of mesh exposure and infection." Def. Ex. G, 2019 Article at 19.
"The inadequacies of the mesh and the TVT lead to long term complications, including but not limited to, pain, acute and chronic pelvic pain, vaginal pain, permanent dyspareunia, injury and pain to partner during sexual intercourse, negative impact on sexual function, the risk of multiple pelvic erosions that can occur throughout one's lifetime, vaginal scarring, vagina anatomic distortion, inability to remove the device, permanent risks for erosions, the need for multiple surgical interventions that carry with them significant risks of morbidity, the development of worsening incontinence and urinary dysfunction … ." Def. Ex. C, TVT Report at 13-14; Def. Ex. D, TVT-O Report at 14.	"Patients may present with vaginal bleeding, discharge, irritation, dyspareunia, or pain for their partner during intercourse … . Failing more conservative therapy, surgery to revise the mesh may be needed. The more aggressive the mesh revision/removal, the greater the likelihood of recurrent urinary incontinence." Def. Ex. G, 2019 Article at 25-26.

Importantly, the 2019 article states that "[i]deally, an implanted material for stress incontinence would lead to incorporation by the body's connective tissue, be permanent, resistant to infection, and inert." Def. Ex. G, 2019 Article, at 19. Dr. Elliott has stated many times that the TVT mesh is none of these. For instance, "many published studies and internal Ethicon studies and documents show that the mesh is not inert and does degrade." Def. Ex. D, TVT-O Report at

14. This degradation results in "chronic infections due to bacterial proliferation at the mesh surface." *Id.* at 16. Dr. Elliott also opine that TVT mesh "is heavyweight and has small pores." *Id.* at 18. More specifically, he has stated that TVT mesh "has a pore size that is much less than 1mm after implantation." *Id.* at 21. Put simply, TVT mesh does not fit any definition of the ideal mesh that the article advocates.

Moreover, a federal court in a remanded Ethicon mesh case has written that "Dr. Elliott is clearly qualified to opine on different types of vaginal mesh products after years of specializing in SUI and his other professional experiences, even though he himself does not recommend vaginal mesh. The fact that Dr. Elliott evidently does not believe that any such devices are safe does not preclude him from comparing or ranking such products." *Wiltgen v. Ethicon, Inc.*, No. 12-cv-2400, 2017 WL 4467455, at *5 (N.D. Ill. Oct. 6, 2017). This article does not change Dr. Elliott's position on TVT mesh devices, and he should be permitted to testify that the TVT devices are unsafe for the surgical treatment of SUI.

Finally, Defendants' argument goes to the weight of the evidence, not its admissibility. *Id.* at *5; *Herrera-Nevarez v. Ethicon, Inc.*, No. 17C3930, 2017 WL 3381718, at *7 (N.D. Ill. Aug. 6, 2017). Defendants are free to cross-examine Dr. Elliott regarding his views of mesh devices. *Herrera-Nevarez v. Ethicon, Inc.*, 2017 WL 3381718, at *7; *cf. In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.*, No. 2007-MD-1871, 2011 WL 13576, at *9 (E.D. Pa. Jan. 4, 2011) (contradiction between expert's opinions and prior committee testimony was a matter for cross-examination). Defendants' motion on this point should be denied.

B. The Amid classification system relied upon by Ethicon is outdated.

While this issue is clearly one for weight, and not for exclusion, Ethicon made further accusations against Dr. Elliott in its Wave 10 reply brief on this same topic, so this section will

briefly address those points. The crux of Defendants' argument was that Dr. Elliott was that the response above was misleading because he argues that the article's references to type I mesh do not encompass the Prolene used in the TVT and similar devices. As the Court can plainly see above, this brief makes no reference to the classification of mesh at all. The point is simply that Dr. Elliott has always opined that larger pore, lighter-weight mesh products are safer, and the article's position is in line with his long-held belief.

Ethicon also tries to argue that the TVT clearly belongs in Class I among mesh devices, based on an outdated standard created by Dr. P.K. Amid. For instance, a 2015 opinion by the IUGA Science Committee urges that "it was inappropriate to rely too heavily on the Amid classification which no longer covers all the available grafts and invalid to recommend Type I polypropylene above all others for vaginal repair." (Slack M, et al., *Comments Submitted by the IUGA*, Scientific Committee on Emerging and Newly Identified Health Risks, attached as Exhibit A). An article published in 2006 concluded that "[c]urrently existing graft classification systems do not apply to the use of grafts in the pelvis." (Willy Davila, *Clinical implications of the biology of grafts: conclusions of the 2005 IUGA Grafts Roundtable*, Int'l Urogynecol J. at S52 (2006), attached as Exhibit B). A 2011 e-mail exchange between Brian Luscombe, an Ethicon product director on mesh products, and Dennis Miller, M.D., an Ethicon physician consultant, is also telling. Mr. Luscombe writes: "As I am sure you know, the world you knew 7-10 years ago on AMID classification is [no] longer even relevant to some extent. What people think they know about mesh is changing." Dr. Miller responds: "Dude, I may need help but I'm not that sad. I am giving a lecture on the topic I have all the current papers and am keenly aware of the changes. I just wanted some stuff for historical perspective." (Miller-Luscombe e-mail exchange, June 27 and June 30, 2011, attached as Exhibit C). Ethicon points out a footnote in

the article that refers to a consensus statement, which then refers to the Amid classification. (Wave 10 Reply at 2-3). But noting in the article directly addresses the Amid classification system, and certainly it would be absurd to conclude that Dr. Elliott has endorsed the Amid system because an article for which he is a corresponding author has a footnote to another article, which then uses a similar definition to Amid.

Ethicon also criticizes Plaintiffs for not including an affidavit from Dr. Elliott, but he is out of the country and unavailable to respond at this time. But Ethicon is right about one thing. There is value in hearing Dr. Elliott's perspective. This is a classic example of an issue for cross-examination, as the issue raised by Ethicon has nothing to do with Dr. Elliott's qualifications or his methodology in formulating his opinions. Ethicon is free to ask Dr. Elliott about any perceived contradictions in front of the jury.

II. Dr. Elliott is qualified to identify noted risks of TVT mesh including its carcinogenic properties and explain that these risks were not included on the relevant IFUs.

Again citing the 2019 article, Defendants mischaracterize the author's statements in an improper attempt to exclude certain statements made by Dr. Elliott in his reports. It is well-known to the parties and the Court that Dr. Elliott has been critical of Ethicon for the lack of information provided to physicians in its warning labels. Dr. Elliott has consistently opined about the risks of implanting mesh, and whether or not those risks appeared in the instructions for use ("IFUs").

The sentence Defendants reference from the article, in full context, states that "[i]n studies to date, **the use of type I polypropylene mesh** in pelvic surgery has not been associated with an increased risk of cancer." Ex. G, 2019 Article at 19 (emphasis added). Again, the 2019 article defines "type I" or "the ideal mesh" as large pore, and monofilament, while Dr. Elliott has explained that TVT mesh is heavyweight and small pore—what the article defines as "type III."

Id.; Def. Ex. D, TVT-O Report at 4. The article notably does not make any statements regarding studies for the risk of cancer from heavyweight, small pore mesh found in the TVT Devices.

Dr. Elliott has additionally explained that the polypropylene mesh in the TVT Devices is made from plastic pellets, and included with these plastic pellets is a material safety data sheet, (MSDS) that provides instructions and information. Def. Ex. D, TVT-O Report at 34-35. Dr. Elliott notes that the MSDS for the TVT and TVT-O polypropylene states that subcutaneous implantation of polypropylene led to local sarcomas in lab rats. Def. Ex. E, TVT-Secur Report at 19. Yet, this startling information regarding use of the plastic and risk of carcinogenicity was never provided to physicians. Def. Ex. D, TVT-O Report at 36.

This Court has already held that an expert urologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU. *Wave 5 Memorandum Opinion and Order* (Doc. No. 6409) at 2; *Wave 7 Memorandum Opinion and Order* (Doc. No. 6522) at 2. *See also Wise v. C. R. Bard, Inc*., No. 2:12-cv-1378, 2015 WL 521202, at *9-10 (S.D. W. Va. Feb. 7, 2015) (finding a urogynecologist qualified to opine on product labeling based on his knowledge and clinical experience); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 719 (S.D. W. Va. 2014) (finding a urologist qualified to opine on the risks of implanting a product and whether those risks were adequately expressed on the product's IFU).

The bottom line is that the carcinogenic properties of polypropylene used for the Defendants' TVT Devices was a noted risk not disclosed to physicians by Ethicon, and Dr. Elliott is qualified to identify noted risks and explain that the risks on the MSDS were not included on the relevant IFUs or in Defendants' product literature. This Court, therefore, should allow Dr. Elliott to identify the risks and the lack of warnings for those risks, as stated in his expert reports.

III. Dr. Elliott should be permitted to offer opinions regarding Ethicon's research, studies, testing, adverse events, and training.

Once again, Ethicon is engaging in the inefficient practice of raising previous attacks on Dr. Elliott that this Court has already addressed. Defendants revisit their argument that Dr. Elliott should not be permitted to testify regarding Ethicon's failure to test its devices, adverse event reporting, and training. Ethicon's briefing on this issue is nearly identical to its prior briefing in Waves 1, 3, 5, and 7. In response, Plaintiffs incorporate their arguments in Section V of Doc. 2952, Section V of Doc. 4558, and Section V of Doc. 5491.

The only difference in Ethicon's brief is that it has again referenced partial, out-of-context statements from the 2019 article, refusing to accept that the article is generally not discussing the TVT devices. As stated above, the 2019 article explains that the ideal mesh should be large pore and monofilament, and use of smaller pore size meshes was associated with mesh encapsulation and high rates of mesh exposure and infection. Def. Ex. G, 2019 Article at 19. Dr. Elliott has made it clear that TVT mesh "is heavyweight and has small pores." Def. Ex. D, TVT-O Report at 18. Moreover, the 2019 article carefully notes several complications specific to TVT devices. It further states that the article does not contain "an exhaustive list of all potential complications," and "the risks of some specific complications vary between the type of sling used." *Id.* at 23. In short, nothing in the article discounts what Dr. Elliott has stated in his reports.

While the 2019 article does state that synthetic midurethral sling placement has been extensively researched, in his reports Dr. Elliott points out, with respect to TVT devices, that "Ethicon has never conducted a long-term randomized controlled trial with safety as a primary endpoint," and there are "very few studies which have actually studied chronic, long term pain with the TVT or TVT-O." Def. Ex. D, TVT-O Report at 40. Nothing in the article explains whether any of the studies were performed by Ethicon, or whether any of the studies included

evaluation of smaller pore, heavyweight mesh. In other words, the article does not contradict Dr. Elliott's opinions. With respect to studies performed outside of Ethicon, Dr. Elliott has noted that "very few are long term randomized controlled studies and none include a primary endpoint of safety." *Id.* Finally, Dr. Elliott has pointed out that recent studies "suggest that the studies assessing risks of synthetic mid-urethral slings to date are poor and that long-term data or evidence lags behind shorter-term studies." *Id.* This opinion in Dr. Elliott's report is in line with the 2019 article, which limits trial results "out to 5 years." Def. Ex. G, 2019 Article at 27. And, in fact, those studies with five years are only retrospective studies and show that the slings "had a decrease in success rates over time, and the treatments no longer met the pre-specified criteria for equivalence … ." Def. Ex. G, 2019 Article, at 22. In addition, one of these studies showed "that the transobturator approach was associated with a two-fold higher risk of reoperation within 5 years compared with the retropubic approach." *Id.* Even with lower quality studies than Dr. Elliot states in his expert opinions (long-term randomized studies), the TVT slings show they have efficacy and safety issues in the long-term.

In Wave 1, this Court reserved ruling on these issues "because the scope of relevant testimony may vary according to differences in state products liability law" and the facts of each particular case, concluding that:

> I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing before the trial court before or at trial.

Wave 1 Memorandum Opinion and Order (Doc. No. 2666) at 13. This Court adopted this holding in its Wave 3 Order noting, "the Court will refrain from engaging in the extremely inefficient practice of continuously reexamining the qualifications, reliability, and relevance of dozens of experts and their numerous opinions." *Wave 3 Memorandum Opinion and Order* (Doc. No. 4152) at 2. The Court should again adopt this reasoning and deny Ethicon's *Motion*.

Alternatively, this Court should reserve ruling on this issue until trial, as it has previously ruled in this MDL.

IV. Dr. Elliott is qualified to testify regarding product warnings.

In each of his expert reports, Dr. Elliott has consistently opined about the risks of implanting mesh, and whether or not those risks have appeared in the various instructions for use ("IFUs"). Def. Ex. C., TVT Report, at 34-37; Def. Ex. D, TVT-O Report, at 37-40. The Court has already ruled that Dr. Elliott can testify as to each of these. With respect to whether Dr. Elliott can opine on "whether other risks should or should not be included in an IFU," Plaintiffs respectfully request that the Court reconsider this issue, due to Dr. Elliott's extensive experience in the testing and development of medical devices and training of residents with regard to IFUs.

Ethicon argues that Dr. Elliott's "curriculum vitae does not identify any additional expertise to render an opinion about the adequacy of Ethicon's IFU … ." However, as reflected in Dr. Elliott's resume, he does have experience in the testing and development of medical devices. Dr. Elliott worked on the initial animal studies and the clinical design for a male incontinence device. He also developed a rectus fascial harvester medical device for which he owns the patent. *See Dr. Elliott's Curriculum Vitae* at 22 (attached as Ex. B to Ethicon's Motion (Doc. No. 4364-2). Dr. Elliott testified concerning his experience in the development of these devices:

> Well … if you look at my CV, I was involved in transurethral enzymatic ablationof the prostate, which I worked with a researcher and the founder of the company and working with the FDA as far as getting it approved, that's when I was a resident. I worked with the design of a new artificially designed urinary sphincter for males…, so we were working on the standards with the companies, and then my own patent.

See Exhibit 1 attached, *Hammons Depo.* at 256:14-22. Dr. Elliott has direct experience with product design and development and the related FDA approval processes.

Moreover, Dr. Elliott has testified that he has extensive experience teaching residents about the intricacies of an IFU. In *Hammons,* he testified as follows:

> Q. As part of your training and teaching of residents, do you have occasion to teach with regard to IFUs, the instructions for use for medical devices?
>
> A. It would be on a daily basis with residents, especially new residents who are coming on my service, we go over the IFUs, if we're using a medical device, and then if there's a new product that comes out, we'll review those.
>
> Q. When you teach residents about the IFU, what are the types of things you focus on when you're actually teaching day-to-day?
>
> A. Well, we go over everything. It depends upon if it's a new resident or not. Let's take a new resident, typical one, it's every six weeks I have a new resident on my service. We sit down, we go over the IFU, we go over the procedure, how it's described and then the various different warnings or potential complications.
>
> Q. As part of that process, have you learned what it is that you're looking for in an IFU and what needs to be taught to physicians to look for?
>
> A. Oh, absolutely.

Ex. 1, *Hammons Depo*. at 10:12-11:9. This experience also provides Dr. Elliott with extensive experience and background in IFUs, to allow him to opine about what should or should not have been in an IFU. Finally, in *Bellew v. Ethicon, Inc.*, No. 13-cv- 22473, Mem. Op. & Order, Dkt. No. 265, (Nov. 20, 2014), this Court held that Dr. Elliot should be permitted to testify regarding "whether Ethicon provided **sufficient guidance** to surgeons through the Prolift [IFU], the Surgical Guide, and any training programs offered." *Id.* at 24 (emphasis added).

In addition to his training and experience as a Urogynecologist, Dr. Elliott has unique expertise in medical device development and training of other physicians regarding IFUs, which permits him to testify on whether certain warnings should have been included in the

IFUs for TVT devices. This Court, therefore, should allow Dr. Elliott to give his opinions regarding warnings, as stated in his expert reports.

V. Dr. Elliott's opinions that non-mesh repairs are safer alternatives are relevant and reliable.

Defendants—again—seek to preclude Dr. Elliott from testifying that non-synthetic mesh SUI repair is evidence of a safer alternative design. The Court has previously rejected these arguments and should do so again by adopting its Wave 1 and Wave 3 orders on these issues.

A. Dr. Elliott's opinions that non-mesh repairs are safer alternatives are relevant.

Ethicon asks that this Court hold that Dr. Elliott's opinions regarding the safety of non-mesh procedures should be declared as irrelevant to all trials in all cases in Wave 10—regardless of the applicable state law and regardless of the evidence, claims, and arguments in a particular case. When faced with this issue previously, the Court wrote:

> *First*, Ethicon argues that Dr. Elliott should not be permitted to testify that alternative procedures are safer than Ethicon's mesh products. Expert testimony on this subject, Ethicon claims, is not relevant. The relevance of this expert testimony is better decided on a case-by-case basis. Accordingly, I **RESERVE** ruling until trial.

Wave 1 Memorandum Opinion and Order (Doc. No. 2666) at 8. To be relevant, evidence must have "any tendency to make a fact more or less probable than it would be without the evidence," and the fact must be "of consequence in determining the action." Fed. R. Evid. 401(a)-(b). Relevance is more appropriately addressed through motions in limine by the trial court as an evidentiary issue depending on the facts of the specific case and the applicable law.

In *Mullins v. Johnson & Johnson*, No. 2:12-CV-02952, 2017 WL 711766, at *2 (S.D. W. Va. Feb. 23, 2017), this Court applied West Virginia law and held that "evidence that a surgical procedure should have been used in place of a device is not an alternative, feasible design in

relation to the TVT." Plaintiffs are mindful that the Court has ruled that under West Virginia law, surgical procedures, specifically, the Burch procedure, is not evidence of an alternative, feasible design in relation to the TVT. *Id*. However, the Court in *Mullins* did not address pubovaginal slings, which is competent evidence of an alternative design product. *See Id.*

Further, *Mullins* should not be read so broadly as to categorically exclude this evidence from all cases. For example, not all states require evidence of a safer alternative design or that such evidence be from another similar product. Moreover, non-mesh repair evidence may be relevant when assessing failure to warn claims, negligence claims, warranty claims, or as impeachment evidence. Courts in other jurisdictions have concluded that proposed alternative designs involving the substitution of one material for another are proper evidence of a feasible and safer alternative design.

In a drug case, this Court held that a jury should decide whether the substitution of natural material for synthetic material constitutes an alternative design under West Virginia law. *See Keffer v. Wyeth*, 791 F. Supp. 2d 539, 548-50 (S.D. W. Va. 2011). In *Keffer*, the issue involved a hormonal replacement therapy drug. *Id.* at 541. The plaintiffs argued that the drug was dangerous because of the synthetic progestin in the drug and asserted that natural material would have been a safer ingredient to use in the drug. *Id.* at 548. The defense argued that the use of a natural material created a different product altogether, and therefore could not be held up as a "safer alternative design," but the court held that the jury should decide whether substituting a natural component for a synthetic component creates an entirely different product. *Id.* at 549. The same reasoning should apply here. The jury should decide whether a product made primarily from native tissue was a safer alternative to mesh products.

Defendants wrongly contend that its argument for excluding non-mesh repair evidence is consistent with "a general principle of product liability law." Def. Br. (Doc. 8081) at 13, n.1. In reality, there is no universal view as to what constitutes an alternative design, and the issue is typically a question for the jury. In its Wave 10 Motion, Ethicon relies upon a Michigan Federal District Court case regarding a polyester hernia device. Def. Br. (Doc. 8081) at 14 (citing *Barnes v. Medtronic, PLC*, 2019 WL 1353880 (E.D. Mich. Mar. 26, 2019)). However, courts in other jurisdictions have concluded that proposed alternative designs involving the substitution of one material for another are proper evidence of a feasible and safer alternative design. *See, e.g., Collins v. Navistar, Inc.*, 155 Cal. Rptr. 3d 137, 159-60 (Cal. Ct. App. 2013) (plaintiffs were entitled to present evidence that the defendant could have made the windshields of its trucks from bilaminated "glass-plastic," rather than single-laminated glass); *Warnke v. Warner-Lambert Co.*, 799 N.Y.S.2d 666, 669 (N.Y. App. Div. 2005) (affirming a jury verdict in favor of a plaintiff who presented evidence that the defendant could have designed its razors using a different type of plastic); *In re: Methyl Tertiary Butyl Ether ("MTBE") Prods. Liability Litig.*, 175 F. Supp. 2d 593, 624 (S.D.N.Y. 2001) (allegations that safer alternatives were available to the fuel additive the defendants included in their gasoline were sufficient to state a claim for design defect); *Barrow v. Bristol-Myers Squibb*, No. 96-689- CIV-ORL-19B, 1998 WL 812318, at *42 (M.D. Fla. Oct. 29, 1998), *aff'd sub nom. Barrow v. Bristol Meyers Squibb*, 190 F.3d 541 (11th Cir. 1999) (breast implants could be designed utilizing saline solution instead of silicone gel fillers); *Branham v. Ford Motor Co.*, 701 S.E.2d 5, 15 (S.C. 2010) (describing as a "design alternative" a manufacturer's "decision to use one type of inferior material as a component part one year, but a superior material the following year"); *Banks v. ICI Americas, Inc.*, 264 Ga. 732, 736 n. 6 (Ga. 1994) (allowing courts to consider "the

feasibility of an alternative design as well as the availability of an effective substitute for the product which meets the same need but is safer"). *See also Sisk v. Abbott Labs.*, No. 1:11CV159, 2012 WL 3155586, at *5 (W.D.N.C. June 19, 2012) (denying motion to dismiss because plaintiffs had plausibly alleged that liquid baby formula was a safer alternative to powder).

Further, whether a proposed alternative design amounts to a completely different product—rather than an "alternative design"—is often a question of fact for the jury. In *Torkie-Tork v. Wyeth*, 739 F. Supp. 2d 895 (E.D. Va. 2010), the plaintiff proposed two alternative designs that she claimed would have decreased the risk of breast cancer in patients taking Prempro, the defendant's hormone therapy drug: (1) a change in the recommended dosage, and (2) the use of natural progesterone instead of synthetic progestin. *Id.* at 900. On the issue of whether these changes would create a new product, the court held that "[t]his is, of course, typically a question of fact, not law" and called upon the jury to decide whether an alternative dosage of the defendant's drug, or the use of a natural progesterone instead of synthetic progestin, would render the defendant's drug an entirely different product. *Id.* at 900-01. The same reasoning should apply here. The jury should decide whether a product made primarily from native tissue was a safer alternative to mesh products.

Defendants cite to excerpts of Dr. Elliott's prior testimony, contending that Dr. Elliott "fully agrees" that the Burch and autologous sling alternatives are not medical devices. *See* Def. Br. at 5. This is misleading; Dr. Elliott testified that native material devices that treat SUI are not medical devices in the sense that they are not man-made. *See* Def. Ex. H at 25:6-11 ("Q: The cadaveric sling is not a medical device, correct? A: Well, it's – it's a device – it's a product that is purchased from the company Coloplast. So I don't think it qualifies. It's

not a man-made device."). Further, in stating that there is no comparison between the TVT and these devices, Dr. Elliott was referring to their safety and complication rates long-term. *See id.* 93:14-21 ("Q: Would you like to see more long-term data on the autologous pubovaginal sling? A: Long-term studies are always going to be important. However, *when we're talking about safety and complications, it's comparing apples to oranges* because there is no medical device placed in those patients that's permanent." (emphasis added)). That is entirely consistent with his opinions in this case that these alternatives are safer than the TVT and TVT-O. Thus, Dr. Elliott should be permitted to testify as to why pubovaginal slings are a safer alternative product to the man-made TVT and TVT-O slings.

Additionally, Defendants do not even address several alternative issues of relevance. The non-mesh repair evidence is admissible as rebuttal to Defendants' oft-repeated contention that the TVT and/or TVT-O devices are the "gold standard" for the treatment of SUI. *See, e.g.*, *Wiltgen v. Ethicon, Inc.*, No. 12-cv-2400, 2017 WL 4467455, at *3 (N.D. Ill. Oct. 6, 2017) (The availability of other safe and effective procedures is admissible to rebut Ethicon's contention that the TVT and similar products are the "gold standard" for treating SUI.); *Herrera-Nevarez v. Ethicon, Inc.*, No. 17C3930, 2017 WL 3381718, at *7 (N.D. Ill. Aug. 6, 2017) (holding same with respect to "TVT-O and similar products").

Dr. Elliott's opinions with respect to non-mesh alternatives are also relevant to the risk-utility analysis in a design defect claim. Federal courts in remanded mesh cases have held that the "availability of other safe and effective procedures (including surgical procedures) to treat the same condition is relevant and admissible to show the utility of a product" under Illinois design defect law. *Wiltgen*, 2017 WL 4467455, at *4 (citing *Herrera-Nevarez*, 2017 WL 3381718, at *7 (holding same)). Such testimony is equally relevant here.

Dr. Elliott's opinions with respect to non-mesh alternatives are also relevant to a negligence claim under West Virginia law. In the product liability context, the manufacturer has a duty to use reasonable care, which means that the manufacturer must use "the amount of care in [designing] the product that a reasonably careful manufacturer … would use in similar circumstances to avoid exposing others to a foreseeable risk of harm." W. Va. Pattern Instructions § 425. A manufacturer's "duty of reasonable care requires him to recognize an unreasonable risk of harm to those who use the products as designed." *Yost v. Fuscaldo*, 408 S.E.2d 72, 76 (W. Va. 1991). In determining whether Ethicon's conduct was reasonable, a jury should consider whether there were other options on the market at the time that were safer and effective for the treatment of SUI. *See Mullins*, 236 F. Supp. 3d at 940, 944 (S.D. W. Va. 2017) (acknowledging that although an alternative design is not required element of a negligence theory, it is "certainly" relevant to the manufacturer's conduct).

The outcomes in these cases only further confirms this Court's original ruling—the relevance of this evidence should be determined on a case-by-case basis by the Court examining the specific facts and law to be applied. Ethicon's Motion should be denied, and the Court should adopt its original ruling reserving this decision for trial.

B. Dr. Elliott's opinions comparing the TVT devices to non-mesh repairs are reliable.

Defendants take issue with Dr. Elliott's comparison of the TVT devices to non-mesh repairs as unreliable, as they did in Waves 3, 5, and 7. As this Court stated in Wave 3, the arguments raised here "are different from previous arguments by only the very slightest of degrees." *In re: Ethicon, Inc. Pelvic Repair Liab. Litig*, MDL 2327, 2017 WL 4769665, at *1 (S.D. W. Va. July 20, 2017) (adopting Memorandum and Order (*Daubert* Motion re: Daniel Elliott, M.D.) entered on August 26, 2016, as to Wave 1 cases in the Wave 3 cases). In reality,

Dr. Elliott has reviewed, analyzed, and discussed all relevant scientific studies and data. He provides scientific support for his opinions and relies on his extensive professional surgical and medical training and experience in reaching his opinions. Plaintiffs incorporate their argument from Wave 3 on this issue as set forth in Sections I and II of Doc. 2952.

Defendants' motion should be denied on this point. Alternatively (as Defendants also alternatively argue), the Court should adopt its ruling from Wave 1, and reserve ruling on this topic "until further testimony may be offered and evaluated firsthand at trial." *In re: Ethicon, Inc. Pelvic Repair Liab. Litig*, MDL 2327, 2016 WL 4500768, at *4 (S.D. W. Va. Aug. 26, 2016).

VI. Dr. Elliott's testimony properly explains the superiority of other synthetic products, notwithstanding his claim that synthetic products overall are inferior.

Ethicon again attempts to argue, just as they did in Wave 5, that Dr. Elliott should not be permitted to suggest that other mesh products, such as TVT and TVT-O, offer a safer alternative to the TVT-Secur. Def. Br. (Doc. 8081) at 19-20. While Dr. Elliott is not an advocate for any synthetic mesh, finding all of them to pose inherent dangers, that does not detract from the reliability of his testimony that mesh products configured differently than the TVT-Secur are safer. Plaintiffs incorporate their Wave 5 arguments on this issue as set forth in Section IV of Doc. 4558. Ethicon's Motion should be denied.

VII. Dr. Elliott's opinions concerning lighter weight, larger pore mesh are reliable.

Ethicon adopted its Wave 3 argument on this issue. Plaintiffs, in turn, adopt their Wave 3 response set forth in Section III.C of Doc. 2952.

VIII. Dr. Elliott should be permitted to explain the unique problems associated with mechanical-cut versus laser-cut mesh.

Ethicon adopted its Wave 3 argument on this issue. Plaintiffs, in turn, adopt their Wave 3 response set forth in Section IV of Doc. 2952. Additionally, the *Herrera-Nevarez* court more

recently addressed Defendants' motion to exclude similar testimony concerning mechanically cut mesh versus laser cut mesh proffered by Dr. Bruce Rosenzweig, another of Plaintiff's urogynecologist experts. *Herrera-Nevarez*, 2017 WL 3381718, at *7. The court ruled that Defendants' argument went to the weight of the evidence, and not its admissibility, and denied the motion. *Id.* The Court should hold likewise here.

IX. Dr. Elliott is qualified to testify about various components and attributes of the mesh devices, including degradation, shrinkage, contraction, and cytotoxicity.

Ethicon adopted its Wave 3 argument on this issue. Plaintiffs, in turn, adopt their Wave 3 response set forth in Section VI of Doc. 2952.

X. Consistent with the Court's prior rulings, Plaintiffs will not offer Dr. Elliott to opine on Defendants' state of mind or marketing strategies, but other disputed categories of testimony in Defendants' "catchall" Section X are relevant and admissible.

Ethicon adopted its Wave 3 argument on this issue in Section X of its brief, as it did in Waves 5 and 7. Plaintiffs, in turn, adopt their Wave 7 response set forth in Section VII of Doc. 5491.

CONCLUSION

For all of the foregoing reasons, Plaintiffs respectfully request that this Court deny Defendants' Motion to Exclude Certain General Opinions of Daniel Elliott, M.D.

Dated: June 17, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 17, 2019, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to CM/ECF participants registered to receive service in this case.

/s/ Thomas P. Cartmell